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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,222	04/11/2001	Ning Qin	ORT-1414	3034

27777 7590 12/27/2006

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EXAMINER	
SHAFER, SHULAMITH H	
ART UNIT	**PAPER NUMBER**
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/833,222	QIN ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,13 and 23* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7 and 13* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/13/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims:

Applicants' communication of 11 October 2006 (in response to Office Action of 15 August 2006) and the Terminal Disclaimer submitted on 11 October 2006 is acknowledged and made of record. Applicants communication of 9 June 2006 in response to Office Action of 7 December 2005 is acknowledged and made of record.

Claims 6 and 8 have been cancelled. Claims 1-3, 5 and 13 have been amended and the amendments made of record. New Claim 23 has been added and made of record. However, claim 23 is withdrawn from consideration. In the response of 1 March 2004 to the requirement for restriction, applicants elected Group I, drawn to nucleic acid molecule of SEQ ID NO:9, encoding SEQ ID NO:10, a vector, a host cell and a method of producing a protein for prosecution. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 23 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-5, 7, and 13 are under consideration.

Withdrawn Objections/Rejections

Specification:

The objection to the specification as not being in compliance with the sequence rules, 37 CFR 1.821-1.825 is withdrawn in view of applicants indication that indicated sequences are, in fact, properly identified by sequence identifiers.

Claims:

All rejections of claims 6 and 8 are withdrawn. Applicants have cancelled the claims thereby rendering all rejections moot.

The provisional rejection of claims 1-5, 7 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 11, 12 and 18 of Application 10/119624 is withdrawn. The terminal disclaimer filed on 11 October 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 7,157,248 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The rejection Claim(s) 1-5, 7 and 13, under 35 U.S.C. 101/112 because the claimed invention is not supported by either a credible, substantial or specific asserted utility or a well established utility is withdrawn in view of Applicants' arguments.

The rejection of Claims 1 (e), (f) and (g), Claims 2, 3 and Claim 13(a) under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants' amendments to the claims.

The rejection of Claims 1, 3, 5-7 and 13 under 35 U.S.C. 102 (a) as being anticipated by Brown and Bertelli (22 March 2001, WO 01/19870 A2) is withdrawn. The rejection of Claim 2 under 35 U.S.C. 103(a) as being unpatentable over Brown and Bertelli (22 March 2001, WO 01/19870 A2) in view of Klugbauer et al. (1999, Journal of Neuroscience 19:684-691) is withdrawn. The Declaration of Dr. Ning Qin filed on 6 June 2006 under 37 CFR 1.131 is sufficient to overcome the Brown and Bertelli reference.

Maintained/New Objections/Rejections

Objections:

Claim 5 is objected to because of the following informalities: "wherein" is misspelled as "herein". Appropriate correction is required.

Claim 13 is objected to because of the following informalities: "capable" is misspelled as "coapable". Appropriate correction is required.

35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 7, as recited reads on host cells, including any eukaryotic cell. There is no limitation wherein the host cells are isolated or in culture, therefore the claims read on transfected cells in a human, and thus are not patentable subject matter. This rejection could be overcome by adding a limitation wherein the host cells are isolated or in culture.

35 U.S.C. § 112, Second Paragraph:

Claims 1-3, 5 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1(a), and 5 have been amended to read "polypeptide having a sequence and biological activities substantially same.....". It is unclear what applicant intends by "substantially same". There is no art-accepted definition of the term, and the term is not defined in the specification; therefore, the metes and bounds of the claim cannot be determined.

Claims 2 and 3 are rejected as being vague and indefinite in reciting "Any of the nucleic acid molecules of claim 1". It is not clear how many of the molecules applicants intend. It is suggested that claims be amended to read "Any one of the.....".

Claim 13 is vague and indefinite in reciting "an $\alpha_2\delta$-4 calcium channel". It is unclear what protein is intended to be encompassed to the term.

Claim 7 is included in this rejection as dependent upon rejected claims.

The rejection of Claim 1(d) for reciting "hybridizes under stringent conditions" is maintained for reasons of record and for reasons set forth below. Applicants traverse this rejection (Response of 9 June 2006, page 10). The reason for the traversal is that the specification provides detailed description and examples on pages 30-31.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons: The specification discloses that any number of art-recognized methods may be used to facilitate accurate identification of nucleic acid targeting to a hybridizable probe (page 30, lines 21-23). The specification goes on to give an example and concludes with the statement "conditions for increasing the stringency of a variety of nucleotide hybridizations are well known in the art" (page 31, lines 15-16). However, the specification does not disclose specific hybridization conditions to be used in the instant invention; and unambiguous definition for "stringent conditions" has not been provided.

35 U.S.C. § 112, First Paragraph:

The rejection of amended Claim(s) 1-3, 5 and 13 for failing to comply with the enablement and written description requirement is maintained for reasons of record and for reasons set forth below. Applicants traverse this rejection (Response of 9 June 2006, page 9). The reason for the traversal is that the claims, as amended, are now directed to an isolated nucleic acid molecule encoding a polypeptide having a sequence and biological activities substantially same as a polypeptide of SEQ ID NO:10. Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons: Nucleic acid molecules encoding polypeptides having a sequence and biological activities substantially same as a polypeptide of SEQ ID NO:10 are not enabled. Since the term "substantially same" does not have an art-accepted meaning and is not defined in the specification, undue experimentation would need to be undertaken by one of skill in the art to determine which of the possible sequences would encode a polypeptide having sequence and biological activity of the polypeptide

of SEQ ID NO:10. It would it would require undue experimentation of one of skill in the art to make and use the claimed invention to the full scope of the claims.

Furthermore, since the term "substantially same" does not have an art-accepted meaning and is not defined in the specification, the claims are drawn to a genus of nucleic acids that encode polypeptides having an undefined similarity to the polypeptide of SEQ ID NO:10. Only a nucleic acid molecule of SEQ ID NO:9 encoding a polypeptide of SEQ ID NO:10, but not the full breadth of the claims meet the written description provision of 35 U.S.C. 112, first paragraph.

The rejection of claim 7 under 35 U.S.C. 112, first paragraph because the specification, while being enabling for an isolated or cultured host cell comprising an expression vector, does not reasonably provide enablement for any generic host cell comprising an expression vector is maintained for reasons of record, and is also applied to claims 5 and 13. Please note, as stated in the previous office action, that this rejection could be overcome by amending the claims to recite, for example, "An isolated recombinant host cell..." because such an amendment would clarify that the claims are directed only to host cells which are to be made and used in culture. Applicants have failed to address this issue in their response.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7 and 13 are rejected under 35 U.S.C. 102 (b) as being anticipated by Klugbauer et al (1999. Jnl of Neuroscience 19:684-691, cited in previous Office Action). Klugbauer et al. teach cloning and expression of two new genes encoding

proteins with essential properties of a calcium channel subunit, $\alpha_2\delta$-2 and $\alpha_2\delta$-3. The nucleic acid encoding $\alpha_2\delta$-3 is 36.1% identical to the nucleic acid of SEQ ID NO:9. As can be seen by the enclosed sequence alignment, the nucleic acid taught by Klugbauer et al. comprises at least 15 sequential bases of polynucleotide of SEQ ID NO:9 (encoding polypeptide of SEQ ID NO:10). Thus, the teachings of Klugbauer et al. anticipate the limits of claim 1. The reference teaches isolation of RNA and cDNA library construction (page 684, 2nd column, last paragraph), thus anticipating the limitations of Claims 2 and 3. The reference teaches the preparation of expression vectors and the transfection of HEK293 cells (page 686, 1st column, 6th paragraph); absent evidence to the contrary, the $\alpha_2\delta$-3 calcium channel subunit has "biological activities substantially same as polypeptide of SEQ ID NO:10"; thus claims 5 and 7 are anticipated. Therefore, the teachings of Klugbauer et al. anticipate all the limitations of Claims 1-3, 5 and 7.

Conclusions

Since new grounds for rejection have been presented, this action is non-final.

Claims 1-3, 7 and 13 are rejected.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHS

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

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  JOURNAL   Submitted (10-SEP-1998) Klugbauer N., Institut fuer Pharmakologie
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ORIGIN

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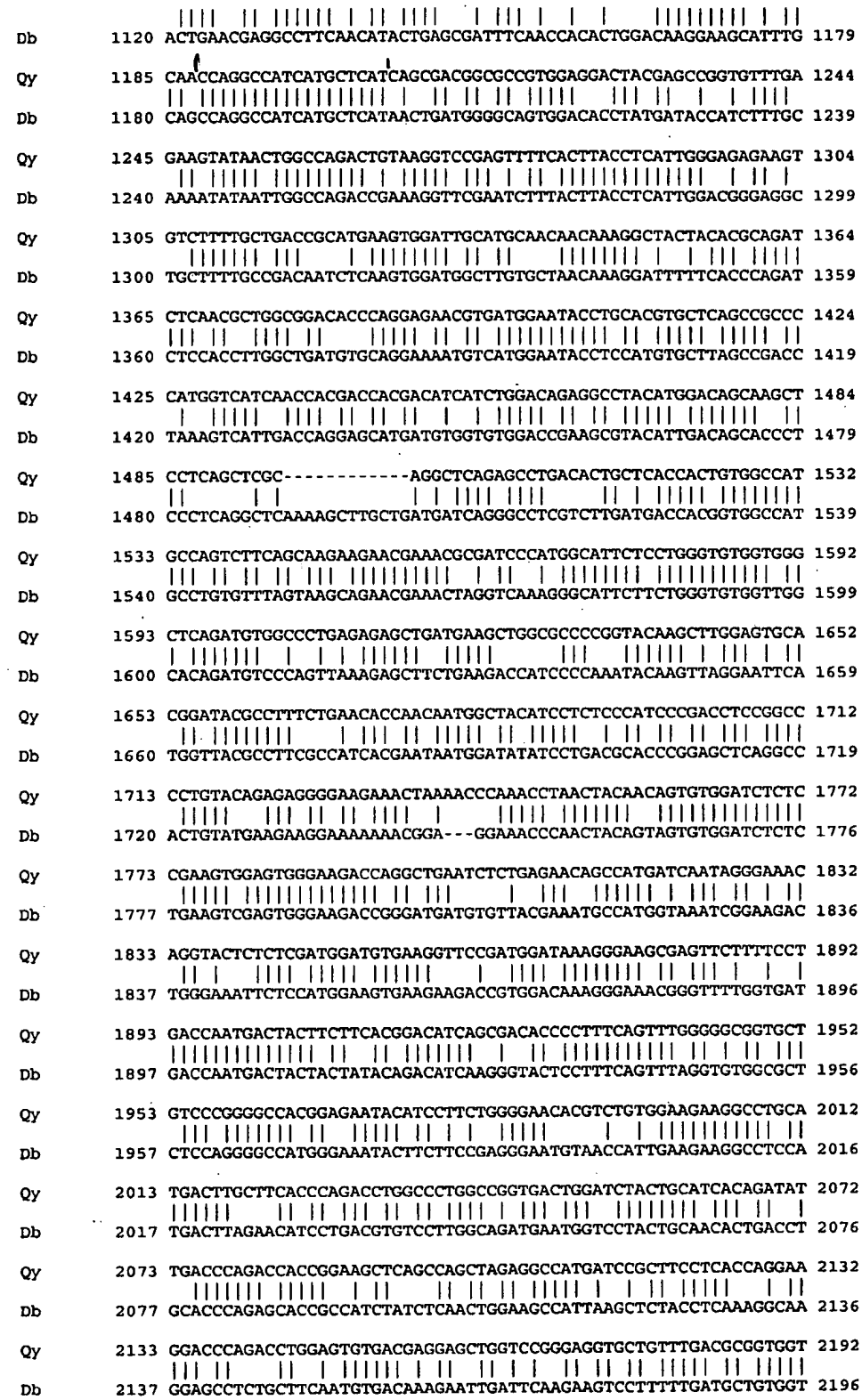

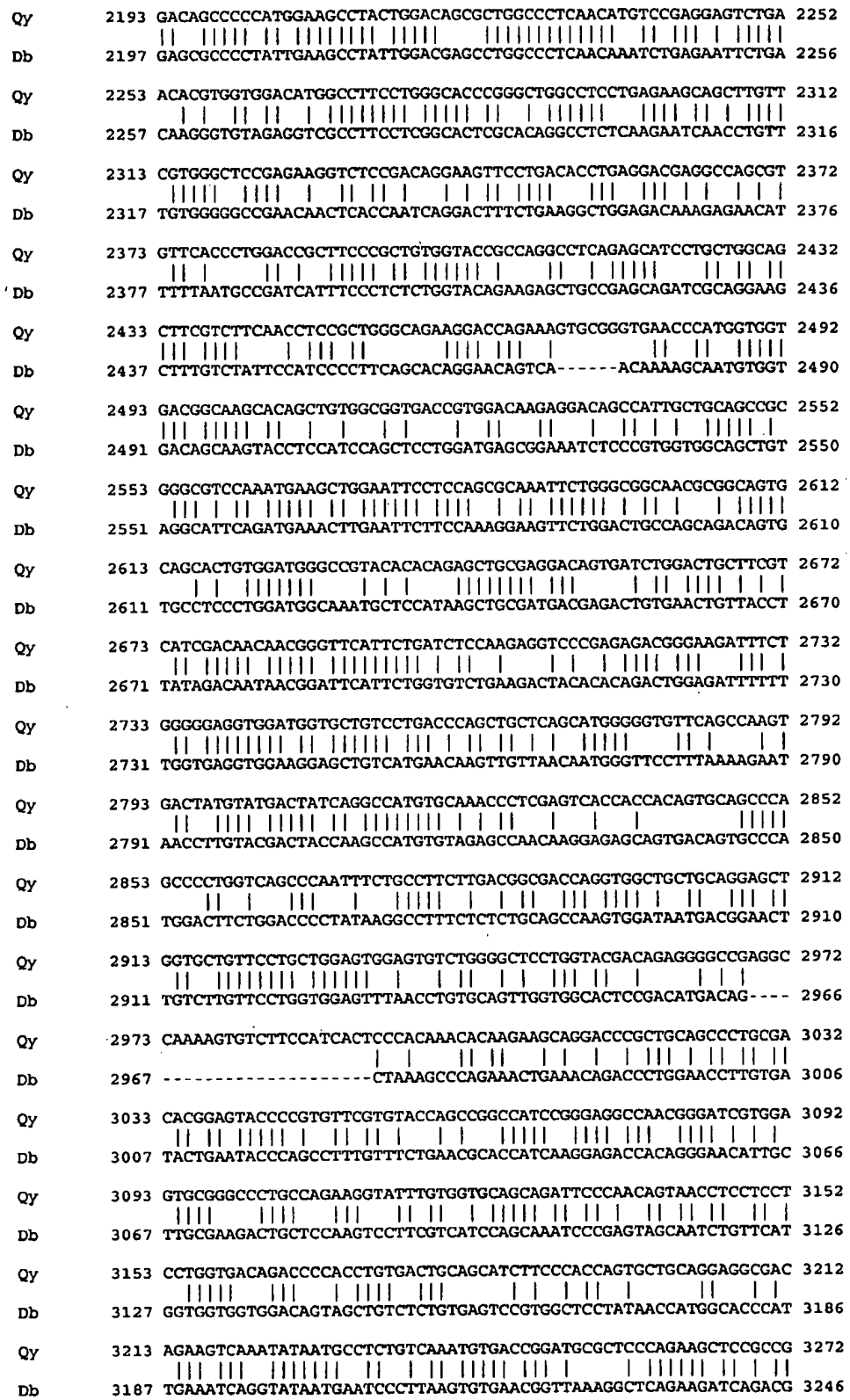

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